Patent Claims

1. Process for the gentle preparation of superfine micro- and nanoparticles with a particle size (average diameter of the number distribution) less than 10 μm, in particular less than 5 μm and more preferably less than 1 μm, characterized in that a matrix material is subjected to a high-pressure homogenizing process in an anhydrous or water-reduced medium and/or at low temperatures under 90°C, preferably room temperature (20°C) and in particular below the freezing point of water, which leads to a gentle particle size reduction with minimization of the impairment of the chemical stability of the homogenized material.

2. Process according to claim 1, characterized in that the homogenized matrix material is drugs (pharmaceutical active ingredients or veterinary drugs) or active ingredients and/or auxiliaries and/or additives for cosmetics, agricultural products, foodstuffs and preservatives.

3. Process according to claim 2, characterized in that the homogenized matrix material is the drugs ciclosporin, azodicarbonamide, paclitaxel, prednisolone, carbamazepine, taxol, morphine, diclofenac, ibuprofen, phenobarbital or cromoglycin.

4. Process according to claim 1, characterized in that the homogenized matrix material is synthetic, semi-synthetic or natural polymers, in particular natural macromolecules.

5. Process according to claim 4, characterized in that the homogenized matrix material is synthetic polymers, in

polyhydroxybutyrate -valeriate co-polymer, polyacryates, polymethacrylates, polyvinyl derivatives, block polymers of

polyethylene glycol and polyesters, polyhydroxybutyric acid, polycyanoacrylates, polycarbonates or polycaprolacton.

6. Process according to claim 4, characterized in that the homogenized matrix material is natural macromolecules, in particular alginates, albumin, preferably serum albumin, human albumin and bovine albumin, collagen, casein, fibrin, tragacanth, xanthans, polysaccharides, in particular chitin, dextrans or hyaluronic acid.

7. Process according to claim 1, characterized in that the homogenized matrix material is polymers or natural macromolecules loaded with drugs or active ingredient.

8. Process according to claim 7, characterized in that the homogenized matrix material loaded with drug or active ingredient is the polymers polylactide, polyglycolide, polylactide/-glycolide co-polymer, polyorthoester, polyhydroxybutyrate (PHB), polyhydroxyvaleriate (PHV), polyhydroxybutyrate/-valeriate co-polymer.

9. Process according to claim 7, characterized in that the homogenized matrix material charged with drug or active ingredient is natural macromolecules, in particular alginates, albumin, preferably serum albumin, human albumin and bovine albumin, collagen, casein, fibrin, bentonite, tragacanth, xanthans, polysaccharides such as chitin, dextrans or hyaluronic acid.

10. Process according to one of claims 1 to 9, characterized in that the materials to be reduced in size are dispersed in

materials to be reduced are dispersed in an oily medium, in particular medium chain triglycerides (MCT), peanut oil, avocado

oil, cottonseed oil, safflower oil, long chain triglycerides (LCT), in particular soybean oil, triacetin or isopropyl myristate.

12. Process according to claim 10, characterized in that the materials to be reduced are dispersed in liquid hydrocarbons, in particular fluid paraffin, viscous paraffin, hexane or octane.

13. Process according to claim 10, characterized in that the materials to be reduced are dispersed in polyethylene glycols (PEGs), in particular PEG 100 to PEG 1000, anhydrous glycerol, anhydrous alcohols, in particular methanol, ethanol, 1-propanol, isopropanol, n-butanol, 2-butanol, pentanol, hexanol, octanol, decanol, allyl alcohol, propargyl alcohol, ethanol, isopropanol and butanol, or propylene glycols.

14. Process according to claim 10, characterized in that the materials to be reduced are dispersed in dimethyl sulfoxide.

15. Process according to one of claims 1 to 9, characterized in that the materials to be reduced are dispersed in a dispersion medium, that contains a small or minimized proportion or proportion desired, for product-related reasons, of water.

16. Process according to claim 15, characterized in that the materials to be reduced are dispersed in a dispersion medium which contains less than 5 wt.-%, in particular less than 1 wt.-%, water.

medium which contains less than 1 wt.-% water.

18. Process according to claim 15, characterized in that the materials to be reduced are dispersed in a dispersion medium which contains less than 50% water.

19. Process according to claim 15, characterized in that the materials to be reduced are dispersed in a dispersion medium which contains less than 99 wt.-%, in particular less than 80 wt.-%, water.

20. Process according to claim 15, characterized in that the materials to be reduced are dispersed in a dispersion medium which contains water in which further substances are dissolved, in particular polymers, preferably polyethylene glycols solid at room temperature, preferably PEG 6000, or cellulose derivatives, in particular hydroxypropyl methylcellulose (HPMC).

21. Process according to one of claims 15 to 20, characterized in that the materials to be reduced are dispersed in a medium according to one of claims 10 to 14, to which a proportion of water has been added.

22. Process according to one of claims 1 to 21, characterized in that the process temperature is above room temperature (20°C), but preferably below 50°C and in particular below 30°C.

23. Process according to one of claims 1 to 21, characterized in that the process temperature is room temperature (20°C), preferably below this, in particular approx. 4°C.

24. Process according to one of claims 1 to 21, characterized

25. Process according to one of claims 1 to 24, characterized in that the process is carried out with the exclusion of oxygen, in particular with gassing with inert gases, preferably nitrogen or argon, or under a vacuum.

26. Process according to one of claims 1 to 25, characterized in that dispersion medium used in the process are degassed before use.

27. Process according to one of claims 1 to 26, characterized in that the high pressure homogenization process is carried out in a piston- gap homogenizer.

28. Process according to one of claims 1 to 26, characterized in that the high-pressure homogenization process is carried out in a jet-stream homogenizer, in particular a Microfluidizer.

29. Process according to one of claims 1 to 26, characterized in that the homogenization process is carried out in a rotor-stator homogenizer with high power density.

30. Superfine micro- or nanoparticle dispersions which can be prepared according to the process according to one of claims 1 to 27.